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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,110	07/03/2006	Robert Peter Millar	20747/300	4173

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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/552,110	MILLAR, ROBERT PETER	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35,37,39-41,43 and 45-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33,35, 37,39-41,43 and 45-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 7-9 and 28, drawn to GNRH antagonists, classified in class 514, subclass 2.

II. Claims 10 and 11, drawn to GNRH agonists, classified in class 514, subclass 2.

III. Claims 35, 37, 39-41, 43 and 52-55, drawn to methods of treating a hormone-dependent disease or condition by administering GNRH analogues, classified in class 514, subclass 2.

IV. Claims 45-51 and 56-60, drawn to methods of modifying GNRH analogues, classified in class 514, subclass 2.

Claims 1-6, 12-27 and 29-33 link(s) inventions I and II. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1-6, 12-27 and 29-33. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, inventions I and II as claimed have materially different effects, antagonists and agonists of GNRH, respectively. The compounds do not overlap in scope because they have different structures and functions. There is nothing of record to show them to be obvious variants.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product such as GNRH agonists.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product such as GNRH antagonists.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, that the process as claimed can be used to make another and materially different product such as a GNRH agonist.

Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, that the process as claimed can be used to make another and materially different product such as a GNRH antagonist.

There would be a serious burden on the examiner to search both the products of Groups I and II. There different chemical structures would require independent search queries. It would be additionally burdensome to search the method claims as well as the product claims because a search for the products would not necessarily overlap with a search for the methods. The

treatment claims are especially broad covering conditions with a wide range of patient populations, symptoms, treatments and etymologies. Finally, it would be burdensome to search the methods of both Groups III and IV because literature describing methods of treating would be unlikely to address methods of making these compounds.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of GNRH antagonists: is [AcD-Nal^{1}, D-Cpa^{2}, D-Pal^{3}, Arg^{5}, D-Lys^{6}, D-Ala^{10}]GnRH; [Ac-Δpro^{1}, D-Fpa^{2}, D-Trp^{3}, D-Lys^{6}]GnRH; Cetrorelix; Ganirelix; Abarelix; Antide; Teverelix; FE200486; Na-Glu; A-75998; A-76154; A-84861; D-26344; D-63153; D21775; ramorelix; degarelix; NBI-42902; Org-30850; detirelix; iturelix; TAK-013; TAK810; AN 207; AcD-Nal-D-Cpa-D-Pal-Ser-Arg-D-Lys-Leu-Arg-Pro-D-Ala-NH_2; Ac-APro-D-Fpa-D-Trp-Ser-Tyr-D-Lys-Leu-Arg-Pro-Gly-NH2; AcD-Nal-D-Cpa-D-Pal-Ser-Arg-D-Lys-Lys-Leu-Arg-D-Ala-NH_2; D-Pal-Ser-Arg-D-Lys-Leu-Arg- Pro-D-Ala-NH_2; AcD-Nal-D-Cpa-D-Pal-Ser-Arg-D-Lys-Lys-Arg-Pro-D-Ala-NH_2; [D-Pyr^{1}-D-Phe^{2}, D-Trp$^{3\text{-}6}$]GnRH; D-Lys^{6}-Antide; Lys^{5}-Antide and Lys^{8}-Antide. The species are independent or distinct because they have different chemical structures.

If Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-9 and 12-33 are generic.

This application contains claims directed to the following patentably distinct species of GNRH agonists: pGlu-His-Trp-Ser-Tyr-D-lys-Leu-Arg-Pro-GlyNH_2; Lupron; Zoladex; Supprelin; Synarel; Triptorelin; Buserelin; leuprolide; goserelin; deslorelin; ProMaxx-100; avorelin; histrelin; nafarelin; leuprorelin and triptorelin. The species are independent or distinct because they have different chemical structures.

If Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 10-27 and 29-33 are generic.

This application contains claims directed to the following patentably distinct species of hormones: estradiol, progesterone, cortisol, corticosterone, estrone, testosterone, dihydroxytestosterone, 11α-hydroxyprogesterone and 21-hydroxyprogesterone. The species are independent or distinct because they have different chemical structures.

If Groups I, II, III or IV are elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-33, 35, 37,39-41,43 and 45-60 are generic.

This application contains claims directed to the following patentably distinct species of globulins: cortisol binding globulin, sex hormone binding globulin, or progesterone binding globulin, or albumin. The species are independent or distinct because they have different chemical structures.

If Groups I, II, III or IV are elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no

generic claim is finally held to be allowable. Currently, claims 1-33, 35, 37,39-41,43 and 45-60 are generic.

This application contains claims directed to the following patentably distinct species of GNRH analogues: [AcD-Nal^{1}, D-Cpa^{2}, D-Pal^{3}, Arg^{5}, D-Lys^{6}, D-Ala^{10}]GnRH; [Ac-Δpro^{1}, D-Fpa^{2}, D-Trp^{3}, D-Lys^{6}]GnRH; Cetrorelix; Ganirelix; Abarelix; Antide; Teverelix; FE200486; Na-Glu; A-75998; A-76154; A-84861; D-26344; D-63153; D21775; ramorelix; degarelix; NBI-42902; Org-30850; detirelix; iturelix; TAK-013; TAK810; AN 207; AcD-Nal-D-Cpa-D-Pal-Ser-Arg-D-Lys-Leu-Arg-Pro-D-Ala-NH_2; Ac-APro-D-Fpa-D-Trp-Ser-Tyr-D-Lys-Leu-Arg-Pro-Gly-NH2; AcD-Nal-D-Cpa-D-Pal-Ser-Arg-D-Lys-Lys-Leu-Arg-D-Ala-NH_2; D-Pal-Ser-Arg-D-Lys-Leu-Arg- Pro-D-Ala-NH_2; AcD-Nal-D-Cpa-D-Pal-Ser-Arg-D-Lys-Lys-Arg-Pro-D-Ala-NH_2; [D-Pyr^{1}-D-Phe^{2}, D-Trp$^{3-6}$]GnRH; D-Lys^{6}-Antide; Lys^{5}-Antide; Lys^{8}-Antide; pGlu-His-Trp-Ser-Tyr-D-lys-Leu-Arg-Pro-GlyNH_2; Lupron; Zoladex; Supprelin; Synarel; Triptorelin; Buserelin; leuprolide; goserelin; deslorelin; ProMaxx-100; avorelin; histrelin; nafarelin; leuprorelin and triptorelin. The species are independent or distinct because they have different chemical structures.

If Groups III or IV are elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 35, 37,39-41,43 and 45-60 are generic.

This application contains claims directed to the following patentably distinct species of hormone related diseases and conditions: fertility, benign prostatic hypertrophy, endometriosis, uterine fibroids, premenstrual syndrome, polycystic ovarian syndrome, hirsutism, acne vulgaris, precocious puberty, acute intermittent porphyfia, cryptoorchidism, delayed puberty,

breast cancer, prostate cancer, uterine cancer and endometrial cancer. The species are independent or distinct because they have different patient populations, symptoms, treatments and etymologies.

If Group III is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 35, 37, 39-41, 43, and 52-55 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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